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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,062	10/19/2001	David Rizzieri	20605/1203866-US1	5735

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
06/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,062	RIZZIERI ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8-10,13,14,18-20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 8-10, 13, 14, 18-20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 1, 2007 has been entered.

2. Claims 1, 3, 8-10, 13, 14, 18-20 and 22-24 are pending.

Claims 1, 13, 14, 18-20, 23 and 24 have been amended.

Claims 2, 4-7, 12, 15-17 and 25 have been cancelled.

Claims 1, 3, 8-10, 13, 14, 18-20 and 22-24 are examined on the merits.

New and Maintained Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1, 3, 8-10, 13, 14, 18-20 and 22-24 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either

that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials is newly made and maintained. Claims 4, 12, 21 and 25 have been cancelled.

Applicants reassert, "the present invention is directed to the new use of a known compound.", see page 6, first full paragraph of Remarks submitted June 1, 2007. Applicants also aver the ^{131}I-labeled chimeric 81C6 monoclonal antibody was described in U.S. Patent No. 5,624,659 and the patent file reveals the antibody's sequence, see page 6, 1st paragraph. Applicants conclude arguments noting they are willing to deposit the hybridoma that produces the 81C6 antibody in a recognized depository once the claims are deemed allowable, see page 6, 3rd paragragh. These points of view and arguments have been considered, but found unpersuasive.

Until the assurances under the Budapest Treaty and/or deposit are met in the instant application the instant rejection is made and maintained for the reasons of record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 1, 3, 8-10, 13, 14, 18-20 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,624,659 (April 29, 1997/ reference 1 from IDS submitted June 14, 2002), and in view of Rizzieri et al. (Blood 94(10), Part 2, Supplement 1: 4339, Abstract #4339 November 1999/ reference 3 from IDS submitted June 14, 2003) is maintained.

Applicants set forth once again the criteria needed to establish a *prima facie* case of obviousness, see page 7 of the Remarks. Applicants assert the currently amended claims including the requirement that the lymphoma is Non-Hodgkin's and treated with an antibody, monoclonal antibody 81C6 and antibodies that bind to the epitope bound by monoclonal antibody 81C6 to tenascin is administered intravenously or intra-arterially is not taught by the prior art references, see page 8, section A. This particular type of administration does not preclude one of ordinary skill in the art from implementing the teachings of both references. And while the cited references may have shown to be unsuccessful in treating brain tumors there not sufficient information teaching away from the combination of the prior art. Applicants continue to assert their claimed method demonstrated unexpected and unobvious results, see bridging paragraph of pages 13 and 14. These points of view are not persuasive for the reasons of record, see bridging paragraph of pages 3-5 of Action mailed December 1, 2006.

A proper and formidable *prima facie* case of obviousness has been established meeting the three basic criteria of a rejection under 35 U.S.C. 103(a), see previous Office Actions. The radiolabeled chimeric monoclonal antibody, ^{131}I -81C6 or therapeutic antibodies (dosage to the patient in the range of 10mCi to 100mCi) of the

disclosed invention are used in the treatment of any tumor that expresses tenascin, see patent, column 2, lines 40-49; bridging paragraph of columns 2 and 3; column 3, line 20-column 4, line 44. And Rizzieri notes non-Hodgkin's lymphomas have increased angiogenesis and microvessel density (MVD) and consequently increased expression of tenascin, see Rizzieri abstract, particulary the last paragraph. Rizzieri plainly "...suggests systemically delivered anti-tenascin antibody may be an effective form of therapy." . Applicants have not provided unexpected results that render the claimed invention unobvious.

The combination of the prior art references' teachings would have lead one of ordinary skill in the art to arrive at the claimed invention at the time with a reasonable expectation of success. Both references provide suggestion and motivation to establish and arrive at the claimed invention, accordingly the rejection is maintained.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
12 June 2007